

**AMENDMENTS TO THE CLAIMS**

Kindly amend the specification as follows:

On page 42, line 7 to the bottom of the page, please replace sections A and B with the following:

**A. Mineral-based**

-insoluble, gel-like precipitate

-mineral formulations are the only adjuvants that are considered safe and effective for use in human vaccines

i. **Aluminum hydroxide (Alhydrogel)**

Superfos chemicals

~~www.superfos.com/index.htm~~

a. **SBAS4**

Aluminum salt combined with monophosphoryl lipid A (MPL)

SmithKline Beecham

~~www.sb.com/index.html~~

ii. **Aluminum phosphate (Adju-Phos)**

Superfos chemicals

~~www.superfos.com/index.htm~~

ii. **Calcium phosphate**

Superfos chemicals

~~www.superfos.com/index.htm~~

**B. Water-in-oil emulsions**

-microdroplets of water, stabilized by surfactant in a continuous oil phase

i. **Freund's Complete Adjuvant (FCA)**

a mixture of a non-metabolizable oil (mineral oil), a surfactant (Arlacel A), and mycobacteria (*M. tuberculosis* or *M. butyricum* in Modified FCA)

Superfos chemicals

~~www.superfos.com/index.htm~~

ii. **Freund's Incomplete Adjuvant (FIA)**

has the same oil/surfactant mixture as FCA but does not contain any mycobacteria

iii. **Montanide Incomplete Seppic Adjuvant (ISA) Adjuvants**

a group of oil/surfactant based adjuvants in which different surfactants

On page 43, line 18 to the bottom of the page, please replace section C with the following:

**C. Oil-in-water emulsions**

-microdroplets of squalene or squalane, stabilized with surfactants in a continuous water phase, developed for human clinical trials when combined with immunomodulators

i. **RIBI ADJUVANT SYSTEM™ (RAS)**

4 components: (1) monophosphoryl lipid A (MPL); (2) trehalose dimycolate (TDM); (3) cell wall skeletons (CWS); (4) *S. typhimurium* mitogen (STM)  
Ribi ImmunoChem Research, Inc.  
[www.ribi.com](http://www.ribi.com)

ii. **MF59**

originally developed with N-acety-muramyl-L-alanyl-2-(1',2'-dipalmitoyl-sn-glycero-3'-phospho)ethylamide (MTP-PE) however when antibody titer was endpoint, MTP-PE was not required for adjuvant activity  
Chiron Corp.  
[www.chiron.com](http://www.chiron.com)

iii. **SBAS4**

combination of monophosphory lipid A (MPL), QS21, and a proprietary oil in water emulsion  
SmithKline Beecham  
[www.sb.com/index.html](http://www.sb.com/index.html)

On page 44, lines 1-6, please replace section C with the following:

iv. **DETOX™**

active ingredients include MPL® (derivative of the lipid A molecule found in gram negative bacteria) and mycobacterial cell wall skeleton  
Corixa Corporation  
[www.corixa.com](http://www.corixa.com)

On page 45, lines 6-29, please replace sections B and C with the following:

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B. Non-ionic block copolymers

-polymers composed of a region of hydrophobic polyoxypropylene (POP) flanked by regions of hydrophilic polyoxyethylene (POE), not biodegradable

- i. **TITERMAX<sup>TM</sup>**  
CytRx Corporation  
~~www.cytRx.com~~

- ~~iv. i.~~ **Syntex Adjuvant Formulation-1 (SAF-1)**  
Roche Bioscience (formerly Syntex Corp., Palo Alto, CA)  
~~www.roche.com/pharma/Index.htm~~

- ~~iv. ii.~~ **SAF-2**

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C. Saponins

-extract of Quillaia saponaria tree, saponin is crude extract of triterpenoids

- i. **Quil A**  
Partially purified saponin
- ii. **Spikoside**  
Partially purified saponin
- iii. **QS21 (Stimulon)**  
Purified, defined entity  
Aquila Biopharmaceuticals, Inc. (formerly Cambridge Biotech Corporation)  
~~www.aquilabio.com/~~
- iv. **ISCOPREP<sup>TM</sup> 703**  
Purified, defined entity
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